K120829

510(k) Summary
(21 CFR Part 807.92)

MAY 30 2012

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Establishment Registration #	3008657535
Address:	1153 Medina Rd Medina, Ohio 44256
Telephone Number:	330-239-7709
Fax Number:	330-239-4216
Contact Person:	Dale Davison
Email:	dale.davison@integralife.com
Date Prepared:	2/29/2012

B. Device Information

Trade Name:	Stainless Steel Spinal System
Common Name:	Pedicle Screw Spinal Instrumentation System
Classification:	**MNI** - Class II per 888.3070(b)(1) – Pedicle Screw Spinal System **MNH** - Class II per 888.3070(b)(1) – Pedicle Screw Spinal System **KWQ** - Class II per 888.3060 – Spinal Intervertebral Body Fixation Orthosis **KWP** - Class II per 888.3050 – Spinal Interlaminal Fixation Orthosis **NKB** – Class III per 888.3070(b)(2) – Spondylolisthesis Spinal Fixation System
Predicate Device:	Stainless Steel Spinal System, Theken Spine, K100970
Device Description:	The purpose of this submission is the addition of alternative varieties of pedicle screws and surgical instruments to provide surgeons with further options for implant placement and deformity correction. The Stainless Steel Spinal System components can be rigidly locked together creating a construct for promoting fusion. The individual implant components are fabricated from medical grade stainless steel alloy 316 LVM described by such standards as ASTM F 138 and ISO 5832-1.
Intended Use:	The Stainless Steel Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system (T1-S2/ilium), a posterior non-pedicle screw fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients. The device is indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.
Material Composition:	Implant grade stainless steel per ASTM F-138.

C. Substantial Equivalence

Integra Spine believes sufficient evidence exists to reasonably conclude that the additional components are substantially equivalent to the predicate device Stainless Steel Spinal System (K1000970 SE), manufactured by Theken Spine, LLC. Substantial Equivalency is based on the design concept; the use of established, known materials; feature comparisons; mechanical testing; indications for use; pre-production quality assurance planning and engineering analysis.

The subject device similarities include:

- The same indications for use
- The same operating principle
- The same biocompatible materials
- Implanted using the same surgical techniques and equipment type
- The same manufacturing environment
- The same sterilization process
- The same packaging configurations

Performance Tests:	Static compression bending per ASTM F-1717 Static torsion per ASTM F-1717 Dynamic compression bending with run out per ASTM F-1717 Static cantilever bending per ASTM F-1798 Static tensile pull test
Summary of Test Data:	Mechanical testing of the subject device consisted of static axial compression, static torsion, and dynamic axial compression in accordance with ASTM F-1717. Static cantilever bend tests were performed in accordance with ASTM F-1798 and static tensile pull tests were performed. The construct performed as designed and met or exceeded all product specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Theken Spine, LLC
% Mr. Dale Davison
Vice President-Engineering
1153 Medina Road
Medina Ohio 44256

MAY 30 2012

Re: K120829
Trade/Device Name: Stainless Steel Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: May 03, 2012
Received: May 04, 2012

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120829

Indications for Use

510(k) Number: **K120829**

Device Name: Stainless Steel Spinal System

Indications for Use:

The Stainless Steel Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system (T1-S2/ilium), a posterior non-pedicle screw fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients. The device is indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120829